REMARKS

1. Finality of Office Action/Entry of Amendments

Kindly withdraw the finality of the current Office Action, or withdraw it and reissue a complete Office Action in view of the following. The current Final Office Action rejects new claims 14 and 15 in view of U.S. Pub. 2002/0114847 A1 to *Peshoff* and U.S. Patent No. 5,899,917 to *Edwards* (at pages 3-5 of the Final Office Action), and the rejections are identical in content to the rejections of now-canceled claims 1-12 set forth at page 4 onward of the prior December 28, 2004 Office Action. However, note that Section 5 (page 6) of our 25 March 2005 Response discussed new claims 14-18, and submitted arguments why these claims are allowable over *Peshoff* and *Edwards*. *These arguments have not been addressed in the Final Office Action,* and thus the final rejection is premature: finality should be withdrawn, or the Office Action should be withdrawn and reissued with the Applicant's arguments addressed, so that the Applicant can decide whether to appeal or take other measures. See MPEP 707.07(f), Answer All Material Traversed ("Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it"); also see Examiner Notes for PTO form paragraphs 7.37 and 7.38 (as reproduced in MPEP 707.07), which require that all relevant arguments by the Applicant be addressed, as well as MPEP 706.07 under "Statement of Grounds" ("the final rejection . . . also should include a rebuttal of any arguments raised in the applicant's reply").

The Final Office Action does not meet the requirements of the foregoing provisions. It merely rejects claims 14-15 on the same grounds previously used to reject claims 1-12, and it does not address the Applicant's arguments regarding the novelty and unobviousness of claims 14-18 over *Peshoff* and *Edwards*. Since the Applicant has no idea why these arguments were not found convincing, this deprives the Applicant of the ability to effectively address the current rejections. *We need to know why our arguments were found to be factually or legally deficient, and we need an opportunity to effectively respond or appeal.* Thus, as per the policies of MPEP 706.07, it is submitted that the finality of the Office Action should be withdrawn, or alternatively, that the Final Office Action be withdrawn and reissued with the Applicant's arguments addressed. If the

Examiner disagrees, it would be appreciated if any Advisory Action would contain a full statement of why it is believed that finality is nonetheless justified, so that the Applicant may better determine whether a Petition to Withdraw Finality under 37 CFR §1.181 is appropriate. In accordance with MPEP 706.07, the Applicant is seeking to define the invention in terms of allowable claims, is not seeking to delay prosecution, and is trying to clarify all issues prior to appeal (if appeal should be necessary) – but to do so, we need to know why our comments regarding *Peshoff* and *Edwards* were found unpersuasive. In case any matters might be more rapidly resolved via telephone, it is noted that contact information for the Applicant's attorney is provided at the close of this Response.

If finality is nevertheless maintained, the present claims are nonetheless believed to be in plain condition for allowance in view of the arguments presented below.

2. Rejection of Claim 18 under 35 USC §112(2)

Kindly withdraw this rejection, which is predicated on the basis that "the claim does not set forth any steps involved in the method/process...." However, note that claim 18 positively recites the step of "applying topically to the affected area an effective amount...." Further, while the rejection states that "'the use of' is not a statutory class of invention", we assert that the claim is an acceptable method/process claim reciting positive steps; see, e.g., MPEP 706.03(a), which notes that "[t]he term 'process' as defined in 35 USC 100, means process, art or method, *and includes a new use* of a known process, machine, manufacture, composition of matter, or material" (emphasis added). Here, since steps are recited, and a "use" is merely a method/process by another name, we submit that claim 18 meets all requirements of 35 USC §112(2).

3. Rejection of Claim 18 under 35 USC §101

As noted in the foregoing Section 2 of this Response, claim 18 is a method/process claim which positively recites steps, and is thus a statutory method/process claim. The cases cited in this rejection are not applicable here, since these cases related to claims of "uses" without any recitations of method/process steps.

4. Rejection of Claims 14-15 under 35 USC §103(a) in view of U.S. Pub. 2002/0114847 A1 to *Peshoff* and U.S. Patent No. 5,899,917 to *Edwards*

To repeat the arguments set forth at Section 5 (page 6 onward) of the prior Response:

> These rejections are traversed because there is no suggestion to combine or modify *Peshoff* and *Edwards* to attain the matter of the current claims. The Office Action notes that Peshoff discloses a composition comprising an effective amount of a zinc derivative to promote the cleansing of wounds and to prevent the deterioration of existing wounds (Office Action, page 5). However, *Peshoff* teaches a preferred effective amount of about 5% to about 20% by weight of the composition (Paragraph 31). In contrast, new independent claim 14 (as well as new independent claims 16 and 18) recites a therapeutically effective amount of zinc oxide ranging from 0.1% (1 mg/g =.001 g/g=0.1% by weight) to 2% (20 mg/g = .02 g/g =2.0% by weight) by weight of the therapeutic composition. Nothing in *Peshoff* would suggest to one of skill in the art to modify the amount of zinc derivative to the significantly lower values currently claimed.
>
> Further, the Office Action notes that *Peshoff* does not teach the use of a heparin derivative and a non-medicinal carrier as recited in the current independent claims 14, 16, and 18, but alleges that it would have been obvious to one of ordinary skill in the art to combine the modified zinc derivative taught in *Peshoff* with the use of heparin taught in *Edwards*. However, *Edwards* does not teach the use of heparin derivatives for use in treating insect bites or stings (or for any other topical purpose), and rather teaches the use of heparin as one of many compounds useful in the prevention of restenosis (col. 15, lines 44-48) and in stent compositions (col. 26, lines 16-22). Thus, *Edwards* is not at all about treatment of bites or external wounds, but is rather directed towards a stent for use within a

lumen/vessel of a human body. Nothing in *Edwards* suggests that heparin would be useful in combination with zinc derivatives for the treatment of insect bites and stings; the fields of use are nonanalogous such that one would not look to the field of stents for a solution to issues in the bite treatment field, nor would one assume that the teachings of *Edwards* would be useful in this field.

Additionally, nothing in *Edwards* suggests that heparin derivatives are beneficially used with non-medicinal carriers such as carboxymethylcellulose, glycerin, polysorbate or water for use in bite treatment. *Edwards* teaches the use of water as a compound with a high susceptibility and absorbance for microwave energy (col. 25, lines 14-19) and as a component in a liquid vehicle electrolyte with sufficient ionic strength to conduct electric current or RF energy (col. 26, lines 5-9). Thus, *Edwards* selects water owing to its electromagnetic qualities, a purpose which is not relevant to the objectives of the current claims. *Edwards* therefore does not truly and objectively teach nor suggest that water is a beneficial non-medicinal carrier for bite treatment compositions, nor does *Edwards* teach the use of other non-medicinal carriers like carboxymethylcellulose, glycerin or polysorbate. Further, *Edwards* provides no suggestion to combine such non-medicinal carriers with heparin and zinc derivatives.

In summary, there is no suggestion in the cited references to modify the therapeutically effective amount of zinc derivative taught in *Peshoff* to the dramatically lower values recited in claims 14 and 16; there is no true suggestion to combine the zinc derivative taught in *Peshoff* with the heparin taught in *Edwards*; and there is no suggestion to modify the use of water taught in *Edwards* (as a material with desirable electromagnetic qualities) to include use as a non-medicinal carrier like carboxymethylcellulose, glycerin or polysorbate. Thus, it is submitted that the current claims are allowable over *Peshoff* and *Edwards*.

5. **Rejection of Claims 14-17 under 35 USC §103(a) in view of U.S. Patent 4,879,282 to *Saliba* and U.S. Patent 5,874,094 to *Costello***

It is initially useful to review *Saliba* and *Costello* to ascertain what they can fairly and objectively be said to suggest to one of ordinary skill in the art. Initially, *Saliba* opines that heparin is useful for treating an *incredible* range of conditions, including ailments as diverse as poisonings, "space-travel sickness,"electrical dysrhythmias of the nervous system, and stomach ulcers (see the Abstract and column 2 line 58 onward), as well as insect bites (see the foregoing, as well as column 7 lines 25-35) – and these ailments can be treated with either topical or injected heparin (see column 6 line 66-column 7 line 11). In essence, *Saliba* contends that heparin is effective when administered in almost any manner, to almost any ailment – and it is questionable whether one of ordinary skill would find this credible. (Note that the USPTO apparently did not, since the *Saliba* claims were restricted to a significantly narrower set of uses.) *Saliba* also notes that when heparin is to be applied topically, it should be applied at concentrations of 1,500 IU - 5,000 IU per ml (see column 6 line 66 - column 7 line 35), and it should be accompanied by an acidic carrier (preferably with a pH of about 5.5); see column 7 lines 11-16.

Costello then discusses a topical cream using aloe vera as its active ingredient, along with vitamin E and zinc oxide (see Abstract; column 3 lines 13-23). The cream contains 3-10 g of aloe vera, 200-900 IU (0.19-9.25 g) of vitamin E, and 0.4-1.5 g zinc oxide per ounce (an ounce being 28.47 g); see column 4 lines 29-36. This equates to a cream containing 10-15% aloe vera, 0.67-32% vitamin E, and 1.4-5.2% zinc oxide (by weight).

When the presently claimed invention is placed out of mind, and the cited references are objectively considered for all they suggest, it cannot fairly be said that one of ordinary skill would be led to combine them to obtain the claimed invention. Initially, even if one regarded *Saliba*'s assertion of heparin-based insect bite treatment as credible, *Saliba* suggests use of heparin in a far greater amount than the amount claimed: 1,500-5,000 IU, as compared to the 100-300 USP (IU) claimed. Thus, even if it is assumed for the sake of argument that an artisan would be led by

Costello to add zinc oxide to *Saliba*, the resulting composition would still not amount to the one claimed.[1]

Further, *Saliba* plainly suggests that one *not* add materials such as zinc oxide to heparin when used topically (as claimed): *Saliba* states that an acidic carrier should be used (with a preferred pH around 5.5), but topical zinc oxide has an approximately neutral (if not basic) pH, ranging between 6.95 and 7.37 – see the accompanying Intox entry (of which only pages 1 and 3 are provided, owing to the length of the entry). Thus, it is contrary to *Saliba*'s suggestions to add zinc oxide to heparin in the manner claimed.

In addition, even if it is assumed for the sake of argument that one *did* regard heparin and zinc oxide as combinable as per *Saliba* and *Costello*, these references also suggest use of a dramatically higher concentration of zinc oxide: *Costello* suggests use of 1.5-4.2 wt% zinc oxide, whereas the claimed invention calls for 1-20 mg/g (i.e., 0.001-0.02 wt%). Thus, even if one combined heparin and zinc oxide as per *Saliba* and *Costello*, the combination would not amount to the one claimed – and this is particularly so when it is also considered that the *Saliba*/*Costello* combination would also have dramatically higher heparin than the claimed combination, as discussed above.

We submit that if *Saliba* and *Costello* are fairly considered without hindsight, they suggest (if anything) that a topical mixture of heparin *and aloe vera* be used: aloe is the key ingredient for *Costello*'s cream, and it has an acidic pH (see, e.g., the attached aloelife reference) – and thus it seems the references suggest that aloe is a useful candidate for combination with heparin. But this is not the claimed invention.

In summary, since *Saliba* suggests that any ingredient added to a topical heparin composition should be acidic (unlike the claimed zinc oxide), we submit that no ordinary artisan

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[1] We note that the Examiner states that "[i]t should be noted that the use of specific amounts of sodium heparin and zinc oxide depends on factors such as the severity and type of the insect bite treated." However, this assertion is in no way supported by *Saliba*: *Saliba* prescribes 1,500 IU *at a minimum* for insect bites and the like, and only goes upward – dramatically so (up to 20,000 IU, see, e.g., column 5 lines 60-61) – from there.

would make the asserted combination. Further, even if one did combine heparin and zinc oxide as per *Saliba* and *Costello*, it would have vastly greater amounts of both heparin *and* zinc oxide than the combination claimed. We therefore submit that claims 14-17 are novel, unobvious, and allowable in view of the cited references.

6. In Closing

If any questions regarding the application arise, please contact the undersigned attorney. Telephone calls related to this application are welcomed and encouraged. The Commissioner is authorized to charge any fees or credit any overpayments relating to this application to deposit account number 18-2055.

For the Applicant,

Craig A. Fieschko, Reg. No. 39,668
DEWITT ROSS & STEVENS, S.C.
Firstar Financial Centre
8000 Excelsior Drive, Suite 401
Madison, Wisconsin 53717-1914
Telephone: (608) 828-0722
Facsimile: (608) 831-2106

ATTACHMENTS:

- Intox entry for Zinc Oxide (pages 1 and 3)
- http://www.aloelife.com/AloeVeraPages/AloeArticle.html

UKPID MONOGRAPH

ZINC OXIDE 

SM Bradberry BSc MB MRCP
JA Vale MD FRCP FRCPE FRCPG FFOM

National Poisons Information Service
(Birmingham Centre),
West Midlands Poisons Unit,
City Hospital NHS Trust,
Dudley Road,
Birmingham
B18 7QH

This monograph has been produced by staff of a National Poisons Information Service Centre in the United Kingdom. The work was commissioned and funded by the UK Departments of Health, and was designed as a source of detailed information for use by poisons information centres.

Peer review group: Directors of the UK National Poisons Information Service.

ZINC OXIDE

Toxbase summary

Type of product

Used in cosmetics, sunscreens, emollient and barrier creams, dental cements and ceramics.

Toxicity

Topical zinc oxide is relatively non toxic.

Zinc oxide inhalation is an important cause of "metal fume fever".

Features

Topical

- Zinc contact sensitivity has been described but zinc oxide is relatively non irritant.

Ingestion

- A metallic taste, nausea and vomiting have occurred following presumed mucociliary clearance (and swallowing) of inhaled zinc oxide particles.
- Nausea, vomiting and abdominal pain have occurred following the consumption of food or drink stored in galvanized vessels. Zinc oxide contributes, in part, to this effect.

Origin of substance

Occurs as the mineral zincite.
Prepared by vapourization of metallic zinc and oxidation of the vapours with preheated air (French process); also from franklinite (American process) or from zinc sulphide.
(MERCK, 1996)

Synonyms

Amalox
Azo - 33
Azodox - 55
Chinese White
C. I. 77947
C. I. Pigment white 4
Emanay zinc oxide
Flowers of zinc
Green seal - 8
Hubbuck's white
Ozide
Permanent white
Philosopher's wool
Red - seal - 9
Snow white
White - seal - 7
Zinc white (DOSE, 1994)

Chemical group

A compound of zinc, a group II B transition metal (d block) element.

Reference numbers

CAS	1314-13-2	(DOSE, 1994)
RTECS	ZH4810000	(RTECS, 1997)
UN	2811	(HAZARDTEXT, 1997)
HAZCHEM CODE	NIF	

Physicochemical properties

Chemical structure
ZnO (DOSE, 1994)

Molecular weight
81.37 (DOSE, 1994)

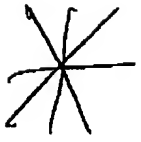
Physical state at room temperature
Solid (MERCK, 1996)

Colour
White or yellowish-white (MERCK, 1996)

Odour
Odourless (MERCK, 1996)

Viscosity
NA

pH
American process zinc oxide pH 6.95; French process zinc oxide pH 7.37. (MERCK, 1996)



Solubility
Water: 1.6 g/L at 28°C.

Aloe Life Whole Leaf Juice Concentrate can help to provide relief from Allergies and Hay fever due to Pollen, Dander, Chemicals, Perfume, Dust Mites and Foods etc.

There are many causes of the discomforts of Allergies. Some of these factors are Digestion, Nutrition, Environment and Hereditary weakness. The number one support in helping to reduce the constant challenge of allergies is to strengthen connective tissue called Collagen. Weak Collagen tissue in nasal passages, lung tissues, and intestinal tract cell walls allow foreign invaders to enter the blood stream and cause an allergy response. By drinking Aloe Life Aloe Vera Juice Concentrate daily and providing the body with needed protein and flavonoids you may begin to reverse allergy sensitivity.

Why does Aloe Life Aloe Vera help?

Aloe Vera has an acidic pH which helps to encourage the body to secrete proper amounts of hydrochloric acid to improve digestion and absorption. Many allergy sufferers have weak digestion which does not allow the body to receive the nutritional benefits from foods and supplements. Once these proper nutrients are received the body can begin to build up the collagen and tissue structure to screen out the allergies. The glycomannan complex present in whole leaf aloe vera helps to provide additional help to strengthen the tissue cell walls. Natural anti-inflammatory and analgesics are found in the yellow sap of the aloe which help to reduce swelling, pain and skin irritation. Campesterol, B-sitosterol, lupeol, and salicylic acid help to promote additional allergy relief.

Skin irritation such as hives, eczema and psoriasis have received great relief from detoxing and cleansing of the liver. To encourage detoxing and liver cleansing drink 1-3 ounces of the Aloe Life Aloe Vera Juice daily along with the Fiber Mate by Aloe Life. Herbal Aloe Detox Formula by Aloe Life can provide even more of a detox. A great formula to take at least once a year (1-3 Months at 1-8 ounces) for a very effective Spring Cleaning of the tissues and liver!

Candida Albicans can also be at the root of the problem. A very pesty fungus that is present in most people in varying amounts. Candida can cause many problems in the body when it is present in large amounts. Symptoms include a white coated tongue, yeast and fungal infections, jock itch, allergy, chemical sensitivity and poor digestion. A diet high in proteins and vegetables and low in carbohydrates and sugars can help to discourage Candida growth, 1-3 ounces of Aloe Life Aloe Vera Juice taken daily, and a good probiotic supplement is helpful.

Contact Aloe Life for more information on Allergies and the Candida Connection. (800) 414-ALOE or by mail at 4822 Santa Monica Ave. #231, San Diego, CA 92107 or email at info@aloelife.com.

These statements have not been evaluated by the Food and Drug Administration. Aloe Life does not intend to diagnose or treat disease.

Aloe Vera

4822 Santa Monica Avenue, Suite 231
San Diego, CA 92107
Phone: (619) 258-0145
FAX: (619) 258-1373
info@aloelife.com